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| APPLICATION NO.             | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------|-------------|----------------------|---------------------|------------------|
| 09/847,538                  | 05/03/2001  | Brita Schulze        | 047664-5002-US      | 4013             |
| 9629                        | 7590        | 05/10/2007           |                     | EXAMINER         |
| MORGAN LEWIS & BOCKIUS LLP  |             |                      |                     | SOROUSH, LAYLA   |
| 1111 PENNSYLVANIA AVENUE NW |             |                      | ART UNIT            | PAPER NUMBER     |
| WASHINGTON, DC 20004        |             |                      |                     | 1617             |
|                             |             |                      | MAIL DATE           | DELIVERY MODE    |
|                             |             |                      | 05/10/2007          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Advisory Action  
Before the Filing of an Appeal Brief**

|                                   |                                    |
|-----------------------------------|------------------------------------|
| Application No.<br><br>09/847,538 | Applicant(s)<br><br>SCHULZE ET AL. |
| Examiner<br><br>Layla Soroush     | Art Unit<br><br>1617               |

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 16 April 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1.  The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
- a)  The period for reply expires 3 months from the mailing date of the final rejection.
- b)  The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2.  The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3.  The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a)  They raise new issues that would require further consideration and/or search (see NOTE below);
- (b)  They raise the issue of new matter (see NOTE below);
- (c)  They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d)  They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4.  The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5.  Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.

6.  Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7.  For purposes of appeal, the proposed amendment(s): a)  will not be entered, or b)  will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: \_\_\_\_\_.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8.  The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9.  The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

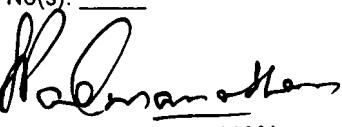
10.  The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11.  The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
see continuation sheet.

12.  Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.

13.  Other: \_\_\_\_\_.

  
**SREENI PADMANABHAN**  
**SUPERVISORY PATENT EXAMINER**

**Continuation Sheet:**

In response to the argument's made over the ODP rejections of copending applications 10/519,193 and 11/018574, Examiner respectfully reiterates " Both sets of copending applications are directed to methods of producing a liposomal preparation comprising a therapeutic agent such as a taxane derivative and a cationic lipid, wherein the liposomes particle size ranges between 50nm to 400nm. The instant claims only differ in reciting the desired zeta potential. However such properties can be optimized by routine experimentation to maximize efficacy of the therapeutic agent. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to practice the scope of the instant claims when in possession of the claims in the copending application."

Examiner has considered MPEP 2131 (II), however in Examiners view the case law does not apply and the argument is not found persuasive. Applicant's argument that the diameter taught by Unger does not anticipate the claims herein is not persuasive. The teachings of the prior art disclose a mean diameter of between 30 nm to 5um, which anticipates the claimed range of 30 nm to 400nm. Similarly, the teachings of Thiery disclose a diameter of between about 200 nm to about 3 um which anticipates the claimed range of 30 nm to 400nm.

Further, Applicant's argument that the prior art does not teach the zeta potential of +30 to about +60 for targeting a composition to an activated vascular site is not persuasive. The prior art teaches the same method of producing cationic liposomal therapeutic system comprising active agents that can target vascular sites. The zeta

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potential of the compounds of the prior art overlap and/or are the same as those claimed. Additionally, since the reference's compositions are prepared by the same steps as the instantly claimed process and further comprise all elemental components of the instantly prepared composition, they would inherently exhibit the same zeta potentials and targeting properties as those instantly claimed, because such functional characteristics of the created composition is inseparable from the describe composition of the references.

Applicant's argue that when the agent is combined with a cationic component, the composition des not necessarily have an isoelectric point above 7 because the agent may have a low isoelectric point to begin with (emphasis added). Examiner respectfully reiterates, since cationic lipids by definition must have a isoelectric point above 7 (see instant specification, pg. 15, at para 0057), absent a showing of unexpected results, it would have been obvious to one of ordinary skill in the art at the time of invention to optimize such parameters during the processes described by either Thierry or Unger by routine experimentations. The ordinary skill in the art would have been motivated to do such optimization to improve stability and delivery of such systems.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).